

# Pelvic organ prolapse, self-image and acceptance

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We hypothesize that patients with pelvic organ prolapse have a lower score on the general and sexual well-being than a healthy control group, but also compared to patients with diabetes mellitus. Furthermore, we hypothesize that sexual self-concept...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON24158

### Bron

NTR

### Verkorte titel

PROSA

### Aandoening

Pelvic organ prolaps and diabetes mellitus type 2

### Ondersteuning

**Primaire sponsor:** none

**Overige ondersteuning:** none

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

1. To determine if and in what way the pelvic organ prolapse influences the sexual function and the self-image of the patient

2. To compare the POP group and the control group on level of sexual function and (sexual) self-concept and to determine whether potential differences are specific to the POP group or can be attributed to disease awareness by comparing the sexual function and (sexual) self-concept between patients with POP and controls, and compare the results to differences between patients with diabetes mellitus type 2 and controls.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

**Rationale:** Pelvic organ prolapse (POP) is a very common disorder among women. Studies show that patients with POP report sexual dysfunction. A study shows that genital self-image is associated with sexual dysfunction. POP directly involves the female genitals and is likely to affect sexual identity. This may become a threat to the sense of the self-concept, which may explain women's fear and negative experiences in sex. Despite its heuristic and clinical significance, the sexual self-concept has received little research attention so far. It is plausible to assume that not only POP, but also other chronic disease influence the self-image and sexual functioning, therefore we want to determine whether the sexual self-concept in relation to sexual function and sexual experiences is specific to POP, or rather determined by general factors related to being chronically ill. It is known that men with diabetes Mellitus (DM) suffer from sexual dysfunction, the sexual function of women with DM on the other hand is less known. The aim of this study is to determine whether and to which extent the pelvic organ prolapse is associated with poor sexual function in heterosexual couples and assess if it is comparable to patients with diabetes mellitus when compared to healthy controls.

**Method:** This is a cross-sectional, observational study in patients with POP-Q stadium 2 and their partners, women with diabetes mellitus type 2 and their partners, and healthy controls and their partners. Eligible patients are recruited from 3 hospitals in the Netherlands. A total of 63 couples in each arm of the study (prolapse, DM and healthy controls) are included. Patients and their partners are asked to fill in questionnaires separately (for female: Female Sexual Function index (FSFI), Female Sexual Distress Scale-Revised (FSDS-R), Body Image Scale, Rosenberg Self-Esteem Scale, Female genital self-image scale, Sexual Self-concept, Hospital Anxiety and Depression Scale (HADS), and SF-36. For men: International Index of Erectile Function, Rosenberg Self-Esteem Scale, Female genital self-image scale, Sexual Self-concept, HADS, and SF-36).

**Main study parameters/endpoints:** The main study endpoint is the score on the FSFI, for women in the POP group, the DM type 2 group, and the control group. Sexual function in men with the international index of erectile function (IIEF), body image using the Body Image Scale and genital body image using the female genital self-image scale (FGSIS), sexual distress with the Female Sexual Distress Scale (FSDS-R), sexual self-concept measured using an adapted version of the Sexual Self Scale of Snell, self-esteem using the Rosenberg Self-Esteem Scale, Anxiety and depression using the Hospital Anxiety and Depression Scale (HADS), and Quality of Life (QoL) measured using the SF-36.

### **Doel van het onderzoek**

We hypothesize that patients with pelvic organ prolapse have a lower score on the general and sexual well-being than a healthy control group, but also compared to patients with diabetes mellitus. Furthermore, we hypothesize that sexual self-concept is an important determinant of sexual function and behaviour. In addition, we hypothesize that a discrepancy of the patient's self-image in comparison to the image of the patient by the partner does exist and can be determinative for the sexual behaviour and functioning.

### **Onderzoeksopzet**

September 2019 start inclusion

### **Onderzoeksproduct en/of interventie**

none

## **Contactpersonen**

### **Publiek**

Radboud UMC  
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### **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

All groups: Women, 40 - 70 years of age, in a heterosexual relationship with sexual contact including penetration

Pelvic organ prolaps group:

- Pelvic organ prolapse POP-Q stadium 2, no further differentiation in stadium

Diabetes mellitus type 2 group:

- Subjects have diabetes mellitus type 2.

Healthy women group

Male partner from every group:

- 40 - 70 years of age.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

All groups: subjects that are not able to give informed consent and subjects who do not understand Dutch

Diabetes mellitus type 2 group:

- Polyneuropathy caused by diabetes mellitus
- Macro vasculopathies caused by diabetes mellitus, defined as:
  - Cerebrovascular accident
  - Myocardial infarction
  - Peripheral vascular disease
  - Suspicion of vasculopathies by clinician on the basis of physical examination and anamnesis
- Primary hypogonadism

Healthy women group:

- Subjects with pelvic organ prolapse or diabetes mellitus.

Male partners from every group:

- Pre-existing sexual dysfunction including erectile dysfunction

## **Onderzoeksopzet**

### **Opzet**

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

## Deelname

Nederland  
Status: Werving gestart  
(Verwachte) startdatum: 05-08-2019  
Aantal proefpersonen: 189  
Type: Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Positief advies  
Datum: 26-07-2019  
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL7906
Ander register	METC Radboud UMC : 2018-4372

## Resultaten